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July 3, 2024

VIA ECF
Hon. Karen S. Marston
James A. Byrne U.S. Courthouse
601 Market Street
Philadelphia, PA 19106

***Re: In re Glucagon-Like Peptide Receptor Agonists (GLP-1RAS) Prods. Liab. Litig.*, MDL No. 3094-**
Letter Brief re: Proposed Case Schedule

Dear Judge Marston:

I. Plaintiffs' Proposed Schedule Is The Most Equitable and Efficient Path To Daubert and Dispositive Motions

Plaintiffs request that this Honorable Court enter the Plaintiffs' proposed Case Management Schedule (attached as Exhibit A and proposed to Defendants in the context of the Rule 26(f) conference) because it allows this Court to manage the MDL in a holistic manner as opposed to the piecemeal manner requested by Defendants. Plaintiffs' holistic proposal gives the Court maximum flexibility, promotes judicial economy, and preserves the constitutional rights of the Plaintiffs—who must be considered in the analysis.

Importantly, Plaintiffs proposal includes an expeditious yet realistic pathway to manage the pretrial proceedings towards the *Daubert* and dispositive motions that Defendants seek without sacrificing the rights of Plaintiffs or requiring a reset for successful Plaintiffs to move forward. Thus, Plaintiffs plan is designed to "promote the just and efficient conduct" of this litigation, 28 U.S.C. § 1407(a), and "to secure the just, speedy, and inexpensive determination," Fed. R. Civ. P. 1, of all cases transferred to this Court for coordinated pretrial proceedings.

Under Plaintiffs' proposal, the motions sought by Defendants will be filed one year from now.[1] Importantly, the Plaintiffs' proposal allows the Court to have the benefit of including Plaintiff-specific facts in its analysis so that it can determine whether the Orders issued on Summary Judgment and Rule 702 will have applicability to broad groups of Plaintiffs. Moreover, in the likely event that some or all of an individual Plaintiff's claims survives, the Court will not have to start from scratch to move the cases forward. These are just some of the reasons why mass

[1] *See* Ex. A, June 30, 2025 deadline for summary judgment motions; July 14, 2025 deadline for Daubert/Rule 702 motions.

tort MDL courts have largely and successfully followed a uniform approach to case management for more than two decades.[2]

Defendants' proposal, on the other hand, would require this Court to serially rule on a series of summary judgment motions without full discovery, without the ability to apply generalized statements to particular facts in anyone's case, and without a plan for moving forward in the event that these motions are not 100% successful. Under this plan, the Parties would be required to wait to commence bellwether discovery until after a decision on the motions—amounting to a delay of at least one year and likely much longer. Defendants' proposal seeks to tee up important issues requiring significant, overlapping fact and expert discovery, in haphazard piecemeal fashion before the parties can fully, fairly, and accurately define and present those issues to the Court for consideration.[3] This inefficiency adds unnecessary expense and time, both of which should be avoided for purposes of judicial efficiency and a just resolution for the injured Plaintiffs.

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[2] *E.g.*, *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, (MDL 2545), Dkt. 467, Dkt. 1588, Dkt. 2866 (MDL was formed on June 12, 2014, first bellwether trial commenced on June 5, 2017; on September 10, 2018, the actions were stayed due to a global settlement); *In re C-8 Pers. Inj. Litig.* (MDL 2433), Dkt. 1, Dkt. 5095 (MDL formed April 9, 2013, first bellwether trial occurring in November 2015 with global settlement occurring in March 2017); *Invokana*, Dkt. 1, Dkt. 218 (CMO No. 20) (MDL formed on Dec. 7, 2016 and case settled in April 2018); *In re Juul Labs, Inc. Marketing, Sales Prac. & Prod. Liab. Litig.,* Dkt. 2 (Oct. 2, 2019); Dkt. 3690 (MDL formed Oct. 2019 and resolved before bellwether process in Dec. 2022); *In Xarelto Prod. Liab. Litig.,* 2:14-md-02592 (E.D. La.) Dkt. 2 (Dec. 17, 2014), Dkt. 13540 (MDL formed Dec. 17, 2014, first bellwether trial occurred 17 months later on April 24, 2016; case resolved a little over three years later on May 6, 2019)

[3] Defendants' propose that plaintiffs be required to combat multiple early summary judgment motions prior to conducting full discovery is tantamount to a request for entry of a *Lone Pine* order and should be rejected at this stage of the litigation. *See Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Superior Ct. Nov. 18, 1986) ("Lone Pine"); *see also Roth v. Cabot Oil & Gas Corp.*, 287 F.R.D. 293, 295 (M.D. Pa. 2012) (describing "so-called '*Lone Pine*' case management order"). *Lone Pine* orders are not expressly authorized by any federal rule so courts typically resort to them "where existing procedural devices explicitly at the disposal of the parties by statute and federal rule have been exhausted or where they cannot accommodate the unique issues of the litigation." *Roth*, 287 F.R.D. at 298, 300; *see also In re Digitek Prod. Liab. Litig.*, 264 F.R.D. 249, 259 (S.D. W. Va. 2010) ("*Digitek*") ("Given a choice between a '*Lone Pine* order' created under the court's inherent case management authority and available procedural devices . . ., I believe it more prudent to yield to the consistency and safeguards of the mandated rules especially at this stage in this litigation."). In addition, "*Lone Pine* orders may not be appropriate in every case and, even when appropriate, they may not be suitable at every stage of the litigation." *In re Vioxx Prods. Liab. Litig*, 557 F. Supp. 2d 741, 744 (E.D. La. 2008) ("*Vioxx*"). Simply put, such case management orders are considered "extraordinary" and typically are only be used after some discovery has been conducted and there exists some questions regarding the plaintiffs' ability to sustain their burden of proof. *See, e.g., In re Davol, Inc./C.R. Bard, Inc. Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-md-2846, 2022 WL 2440295, at *2 (S.D. Ohio July 5, 2022) (explaining limited circumstances where *Lone Pine* order is appropriate); *Roth*, 287 F.R.D. at 297 (denying request for *Lone Pine* order and stating they are utilized most often where, among other things, "the plaintiff's ability to sustain their burden of proof was found to be questionable"); *Digitek*, 264 F.R.D. at 259 (factors for *Lone Pine* order "not presented at this time"); *Vioxx*, 557 F. Supp. 2d at 744-45 (finding *Lone Pine* order appropriate because of the advanced stage of the litigation including voluminous discovery and noting that such an order "may not have been appropriate at an earlier stage before any discovery had taken place"); *In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig.*, MDL No. 2848, 2022 WL 17477553 (E.D. Pa. Dec. 6, 2022) (*Lone Pine* order entered after four years of litigation, voluminous fact and expert discovery, and court granting summary judgment in four bellwether cases). Defendants have not offered any support for entering such an extraordinary case management order at this stage of the litigation."

Plaintiffs recognize that the issues suggested by Defendants for early treatment – issues of general causation, specific causation, sufficiency of warnings, and preemption – are all issues that Defendants have a right to bring before the Court through legal motions at appropriate times. But the bevy of issues that Defendants seek to frontload as "cross-cutting" motions are, in fact, core issues litigated in nearly every pharmaceutical failure to warn case and require full discovery and development of the facts. They touch upon nearly every element of the claims in this MDL and indeed on many aspects of a plaintiff's individual case. There is no surgical way to limit discovery into these issues that does not overlap into other core issues of liability, causation and damages.

These issues cannot be effectively litigated in a vacuum, under some expedited schedule, and some cannot be devoid of any plaintiff-specific or patient-specific facts or context. Take, for example, a proposed "cross-cutting motion" by Defendants on the topic of a gastroparesis diagnosis. To respond to such a motion, discovery would be required as to each individual's medical history, depositions of treating physicians, a case-specific expert analysis of each individual's differential diagnosis and a general expert analysis of the circumstances and basis for a gastroparesis diagnosis, along with discovery from those experts. Discovery would also be required of Defendants in order to determine the corporate conduct and methods by which gastroparesis was (or was not) considered and diagnosed in clinical studies and was (or was not) addressed and reported to the FDA. This is the same substantive discovery that would occur under the bellwether process.

Moreover, there is no early evidence suggesting that Plaintiffs are unlikely to be successful in opposing Defendants' motions. To the contrary, the FDA has stated it would review further safety information about these drugs and request that the manufacturers update their labeling as needed. Discovery into the long history of safety information in the Defendants' files compared to what was submitted to FDA will reveal whether preemption is warranted. And Plaintiffs' general causation case—from gastroparesis to ileus/bowel obstruction, gallbladder and DVT—is well supported. Defendants' GLP1 drugs work, in part, by slowing gastric emptying to a degree (and likely, to a much greater degree in injury cases). Well-designed observational studies confirm a tripling or quadrupling of the risk of these injuries with GLP1 drugs. Even insurers have taken note of the clinical concerns with these drugs and, in some cases, dropped coverage for the drug.[4]

In sum, the most efficient and practical approach is to allow discovery to proceed and provide an opportunity following the completion of discovery for any cross-cutting motions. Plaintiffs' proposal of a fair, expeditious schedule for general discovery and case-specific discovery for a chosen number of bellwether plaintiffs will provide the Court with the best, factual foundation to decide these issues, in the shortest amount of time, and with the least amount of burden to the parties.

II. Plaintiffs' Schedule Has Been Tested In Past MDLs

Plaintiffs' schedule is based on the following fundamental principles:

[4] *See* https://www.bcbs.com/press-releases/most-americans-stop-weight-loss-drugs-before-seeing-meaningful-benefit (last visited July 3, 2024).

(1) Discovery, including discovery needed for the Court's evaluation of preemption arguments, can only be obtained and produced as part of general discovery;
(2) Case-specific discovery for the bellwether selection process should proceed in parallel to general discovery;

(3) Both general and case-specific discovery should proceed promptly so that bellwether selection can be completed in April 2025 and Rule 702 and summary judgment can be briefed by June 2025.

Courts have regularly adopted parallel general discovery and bellwether schedules and have seen litigations that move efficiently. For example, in *Vioxx*, the MDL was formed in February 2005 and discovery commenced shortly thereafter. *In re Vioxx Prod. Liab. Litig*., (MDL 1657), 2012 WL 6045910 at *2 (E.D. La. Dec. 4, 2012) (summarizing litigation). After a reasonable period for discovery, the Court assisted the parties in selecting and preparing six bellwether cases for trial. The first bellwether trial concluded less than one year after the MDL was formed and settlement followed. *Id*.

Indeed, most MDL courts reject bifurcated discovery. Simply put, as indicated in the chart below, bifurcation of general and bellwether case management is not the norm.

Date	MDL	Bifurcation
6/21/2005	*In re Vioxx Prod. Liab. Litig.,* Case No. 2:05-MD- 01657, MDL No. 1657 (E.D. La.), ECF No. 472, pp. 4–6 (Pretrial Order No. 17 permitting discovery to proceed in individual cases)	**No**
7/3/2006	*In re Mirapex Prod. Liab. Litig.*, Case No. 07-1836, MDL No. 1836 (D. Minn.), ECF No. 26, p. 1 (adopting the schedule previously agreed on in 15 individual cases opening all fact discovery and providing date for expert disclosures without bifurcation)	**No**
8/7/2007	*In re Ortho Evra Prod. Liab. Litig.*, Case No. 1:06- 40000, MDL No. 1742 (N.D. Ohio), ECF No. 148, PageID#: 740 (CMO 20 permitting generic expert discovery to proceed simultaneously with fact discovery in bellwethers)	**No**
5/22/2008	*In re Trasylol Prod. Liab. Litig.*, Case No. 1:08-md- 1928, MDL No. 1928 (S.D. Fla.), ECF No. 60, p. 1 (Pretrial Order No. 4 setting initial schedule without bifurcation)	**No**

9/24/2008	*In re Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, Case No. 1:08-GD-50000, MDL No. 1909 (N.D. Ohio), ECF No. 180, PageID#: 1633 (CMO 8 contemplating simultaneous close of general causation and case-specific expert discovery).	**No**
10/13/2010	*In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prod. Liab. Litig.*, Case No. 3:09-md- 02100, MDL No. 2100 (S.D. Ill.), ECF No. 1329, PageID#: 4849 (Amended CMO No. 24 providing bellwether process and case specific core discovery and further discovery when a trial pool is established)	**No**
2/24/2010	*In re Chantix (Varenicline) Prod. Liab. Litig.*, Case No. 2:09-cv-02039, MDL No. 2092 (N.D. Ala.), ECF No. 25, pp. 6–9; 21–23 (Pretrial Order No. 4 ordering fact discovery to proceed in tandem with expert discovery on general causation and liability)	**No**
10/03/2012	*In re Pradaxa (Dabigatran Etexilate) Prod. Liab. Litig.*, Case No. 3:12-md-02385, MDL No. 2385 (S.D. Ill.), ECF No. 42 (CMO No. 6 Unified Case Management Plan)	**No**
10/19/2012	*In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, Case No. 1:11-cv-05468, MDL No. 2272 (N.D. Ill.), ECF No. 653 (Parties' Revised Joint Submission Regarding Representative Trial Plan)	**No**
4/1/2013	*In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, Case No. 12-MD-2342, MDL No. 2342 (E.D. Pa.), ECF No. 287 (discovery not bifurcated)	**No**
8/1/2013	*In re EI DuPont De Nemours and Co. C-8 Personal Injury Litig.*, Case No. 2:13-md-2433, MDL No. 2433 (S.D. Ohio), ECF No. 30 (CMO No. 2 implementing discovery phase to include merits and general causation discovery)	**No**
10/1/2013	*In re Tylenol (Acetaminophen) Mktg., Sales Practices, and Prod. Liab. Litig.*, Case No. 2:13-md-92456, MDL No. 2436 (E.D. Penn.), ECF No. 68.	**No**
11/6/2014	*In re Testosterone Replacement Therapy Prod. Liab. Litig.*, Case No. 1:14-cv-01748, MDL No. 2545 (N.D. Ill.), ECF No. 407, PageID#: 5364 (denying the defendants' request to bifurcate causation and merits discovery).	**No**

10/30/2015	*In re Cook Med., Inc. IVC Filters Mktg., Sales Practices and Prod. Liab. Litig.*, Case No. 1:14-ml- 02570, MDL 2570 (S.D. Ind.), ECF No. 8, PageID#: 29 (order denying the defendant's motion to bifurcate noting it could "complicate the scope of bifurcated discovery and generate avoidable discovery disputes")	**No**
12/24/2015	*In re Ethicon Inc. Power Morcellator Prod. Liab. Litig.*, Case No. 15-d-2652, MDL No. 2652 (D. Kan.), ECF No. 80, pp. 3–6; 9–14 (Scheduling Order No. 1)	**No**
4/26/2016	*In re Fluroquinolone Prod. Liab. Litig.*, Case No. 15- 2642, MDL No. 2642 (D. Minn.), ECF No. 155, p. 1 (initial Case Management Plan opening all fact discovery without bifurcation)	**No**
11/29/2016	*In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig.*, Case No. 18-md-2848, MDL No. 2848 (E.D. Penn.), ECF No. 94, p. 1 (Pretrial Order No. 47 opening all fact discovery); ECF No. 691, p. 3 (Pretrial Order No. 346 aligning general causation and case-specific expert discovery)	**No**
5/1/2017	*In re Invokana (Canagliflozin) Prod. Liab. Litig.*, Case No. 3:16-md-2750, MDL No. 2750 (D.N.J.), ECF No. 218, PageID#: 1098 (CMO No. 20)	**No**
7/21/2017	*In re Taxotere (Docetaxel) Prod. Liab. Litig.*, Case No. 16-md-02740, MDL No. 2740 (E.D. La.), ECF No. 669, p. 4, ¶¶ 6, 8 (CMO No. 3 aligning fact and expert discovery)	**No**
9/7/2017	*In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices and Prod. Liab. Litig.*, Case No. 3:16-md-2738, MDL No. 2738 (D.N.J.), ECF No. 693, PageID#: 5118 (CMO No. 9 setting discovery deadlines without bifurcation)	**No**
4/11/2018	*In re Nat'l Prescription Opiate Litig.*, Case No. 1:17- CV-2804, MDL No. 2804 (N.D. Ohio), ECF No. 232, PageID #1095–1101 (CMO No. 1)	**No**
5/18/2018	*In re Proton-Pump Inhibitor Prod. Liab. Litig.,* Case No. 2:17-md-2789, MDL No. 2789 (D.N.J.), ECF No. 116, PageID#: 1322, ¶ 2 (denying the defendants' motion to consider general causation and preemption before conducting case-specific fact discovery)	**No**
5/20/2019	*In re Aqueous Film-Forming Foams Prod. Liab. Litig.*, Case No. 2:18-mn-2873, MDL No. 2873 (D.S.C.), ECF No. 99, p. 1 (CMO No. 4)	**No**

6/20/2019	*In re 3M Combat Arms Earplug Prod. Liab. Litig.*, Case No. 3:19-md-2885, MDL No. 2885 (N.D. Fla.), ECF No. 452, pp. 2–3 (CMO No. 2)	**No**
4/30/2021	*In re Elmiron (Pentosan Polysulfate Sodium) Prod. Liab. Litig.*, Case No. 2:20-md-02973, MDL No. 2973 (D.N.J.), ECF No. 35, PageID#: 346 (CMO No. 7 opening initial discovery); ECF No. 42, PageID#: 441 (CMO No. 9 ordering parties to implement bellwether discovery)	**No**
12/3/2021	*In re Paraquat Prod. Liab. Litig.*, Case No. 3:21-md- 3004, MDL No. 3004 (S.D. Ill.), ECF No. 587, PageID#: 1604–05 (CMO No. 12)	**No**
11/11/2022	*In re Abbott Labs., et. al., Preterm Infant Nutrition Prod. Liab. Litig.*, Case No. 1:22-cv-00071, MDL No. 3026 (N.D. Ill.), ECF No. 278, PageID# 3674 (order declining to adopt defendants' proposed discovery schedule)	**No**
7/6/2023	*In re Hair Relaxer Mktg., Sales Practices, and Prod. Liab. Litig.,* Case No. 1:23-cv-00818, MDL No. 3060 (N.D. Ill.), ECF No. 146 (minute entry declining "to adopt Defendants' proposal (Dkt. 125 at 6) requesting prioritizing 'general causation' discovery")	**No**
12/28/2023	*In re Uber Technologies, Inc. Passenger Sexual Assault Litig.*, Case No. 3:23-md-03084, MDL No. 3084 (N.D. Cal.), ECF No. 175, pp.7–8 (Pretrial Order No. 5)	**No**
1/2/2024	*In re Paragard IUD Prod. Liab. Litig.*, Case No. 1:20- md-02974, MDL No. 2974 (N.D. Ga.), ECF No. 605, pp. 2–3 (CMO and Second Amended Scheduling Order).	**No**
1/26/2024	*In re Social Media Adolescent Addiction/Personal Injury Prod. Liab. Litig.*, Case No. 4:22-md-03047, MDL No. 3047 (N.D. Cal.), ECF. No. 579, p. 1 ("The request for early resolution of the general causation issue was DENIED for the reasons articulated on the record.")	**No**
5/1/2024	*In re Tepezza Mktg., Sales Practices, and Prod. Liab. Litig.*, Case No. 1:23-cv-03568, MDL No. 3079 (N.D. Ill.) (the court denied defendant's proposal for staggering expert and merits discovery at the CMC on May 1) (transcript has been ordered and will supplement this filing once received)	**No**

6/24/2024	*In re Suboxone (Buprenorphine/Naloxone) Film Prod. Liab. Litig.,* Case No. 1:24-md-3092 (N.D. Ohio) ECF No. 103 (declining "Defendants' request to sequence discovery by proceeding first with discovery related to general causation, limiting case-specific discovery and discovery related to marketing, promotion, and other issues that generally apply to all cases in this MDL")	**No**

III. Plaintiffs and Defendants Have Reached Agreement on Motions Related to Product Identification And that Process Is Incorporated in the Parties' Plaintiff Fact Sheet and Enabling Order

Plaintiffs met and conferred with Defendants on the issue of product identification, *i.e.*, proof of use of the product(s) at issue in this litigation. The Plaintiff Fact Sheet ("PFS") and its associated Enabling Order, Section II.D and III provides a timeframe for each Plaintiff to submit product identification. After an appropriate cure period, if Plaintiff fails to submit product identification Defendants may move for an Order dismissing Plaintiff's complaint. This process, agreed to by the parties, will allow for cross-cutting dismissal of any Plaintiff who does not demonstrate appropriate product identification early in the litigation. **To the extent a Plaintiff identifies a product that is compounded or counterfeit, the parties are in agreement that these cases would need a dismissal mechanism similar to the format in the Enabling Order.**

IV. Defendants' Proposal for Accelerated Summary Judgment Motions is Inefficient and Embeds Needless Expense and Delay.

Defendants' proposed "cross cutting" summary judgment motions are neither cross-cutting nor would they accelerate the resolution of the litigation. To the contrary, under Defendants' proposal, the litigation would languish.[5] [6] Plaintiffs believe Defendants' proposal would require a minimum of one year to allow for document production, depositions, other discovery requests, expert reports and depositions, and finally, dispositive motions. This timeline would defer, likely for years, the development of important information normally obtained through the bellwether process. Such information is fundamental to the management of all cases in an MDL like this one.[7] Additionally, Defendants' proposed schedule would create needless additional costs and

[6] Importantly, without the context of an individual set of facts related to a particular plaintiff, it is impossible to know the number and complexity of motions on any single issue of the multitude that they raise. For example, Defendants may seek a ruling related to issues of federal preemption. Presumably, that would require defendants to file motions on each and every disease alleged in this MDL and file a motion related to preemption for each. It is hard to see how defining the warning at issue and the injury at issue for a particular time period when the warning was in effect will not aid the Court.

[7] *See In re Actos (Pioglitazone) Prod. Liab. Litig*., 274 F. Supp. 3d 485, 498 (W.D. La. 2017) (noting that the dual-track plan with both general causation and bellwether discovery proceeding simultaneously allowed defendants to better understand their potential liability in the case); *In re E. I. Du Pont De Nemours & Co. C-8 Pers. Inj. Litig*., No. CV 2:13-MD-2433, 2019 WL 2088768, at *8 (S.D. Ohio May 13, 2019) (noting that bellwether cases were chosen

inefficiencies for the parties relating to new and supplemental depositions and reports of medical and scientific experts.

Moreover, courts have been hesitant to apply rulings on cross-cutting motions to individual cases in an MDL. The Supreme Court has emphasized that cases within an MDL "retain their separate identities" absent affirmative elections by plaintiffs.[8] As one MDL court recently explained, citing a Third Circuit decision, "This individuality requirement in an MDL ensures that each litigant's rights are respected while their cases are consolidated for pretrial proceedings under 28 U.S.C. § 1407."[9] As the Third Circuit explained, in declining to apply the law of the case across individual actions, "[N]either MDL centralization nor any other procedural device can impose the heavy toll of a diminution of any party's rights."[10] While "[s]ome purely legal issues may apply in every case," questions that turn "on the existence or nonexistence of historical facts unique to each Plaintiff… are not amenable to across-the-board resolution."[11] As explained below, many of the issues that Defendants claim to lend themselves to early and across-the-board resolution are instead likely to turn on case-specific facts, such that resolution of one case will offer only limited information to other plaintiffs, while adding unnecessary delay and costs to this litigation.

A. Early Summary Judgment on Whether Plaintiffs Need a Prior Medical Diagnosis and a Test to Support a Gastroparesis Diagnosis Will Not Advance the Litigation

Defendants' apparent position on gastroparesis diagnosis is an example of the need for full discovery to accurately address the issue. While Defendants failed to inform doctors of the need to monitor GLP-1 RA-prescribed patients for gastroparesis, or to conduct a test if symptoms of gastroparesis manifest, they now contend that a prior medical diagnosis of gastroparesis and specific results from an objective test are required to prove a plaintiff's injuries. Defendants are wrong. First, Plaintiffs do not need a prior diagnosis of gastroparesis to pursue their claims—although many plaintiffs do have such a diagnosis.[12] Plaintiff must only produce a combination of factual and expert evidence to demonstrate the existence of a genuine issue of fact on the issue for it to reach the jury. This is not capable of assessment without the particular facts of a claim.

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within the first few months of the MDL to provide "'meaningful information and experience to everyone involved in the litigations'") (quoting Eldon E. Fallon, Jeremy T. Grabill, Robert Pitard Wynne, Bellwether Trials In Multidistrict Litigation at 2332, Tulane Law Review (2008)).

[8] *Gelboim v. Bank of America Corp*., 574 U.S. 405, 413 & n.3 (2015)

[9] *In re Paraquat Prod. Liab. Litig*., No. 3004, 2023 WL 3948249, at *2 (S.D. Ill. June 12, 2023) (citing *Home Depot USA, Inc. v. Lafarge North America, Inc.*, 59 F.4th 55, 65 (3d Cir. 2023)).

[10] *Home Depot*, 59 F.4th at 62 (internal quotation and citation omitted).

[11] *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig*., 852 F.3d 268, 302 (3d Cir. 2017), vacated and remanded sub nom. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 139 S. Ct. 1668, 203 L. Ed. 2d 822 (2019)).

[12] A definitive diagnosis of a particular injury is not necessary for filing a lawsuit. In similar circumstances, the Third Circuit Court of Appeals has concluded that a definitive diagnosis is not required to start the statute of limitations for filing a lawsuit. *Debiec v. Cabot Corp.*, 352 F.3d 117 (3d Cir. 2003). The Court's analysis is applicable to the requirements to file a case. *In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig.*, No. MDL 2848, 2022 WL 17477553 (E.D. Pa. Dec. 6, 2022), does not support Defendants' proposal that the Court require proof of a gastric emptying study for gastroparesis claims. In *Zostavax*, the plaintiffs' experts agreed that there was as specific test necessary to conclusively diagnose one of the injuries at issue (shingles). *Id.* at *2. Here, gastroparesis is a more complex, clinical diagnosis. Further, what Defendants call "earlier" summary judgment and Rule 702 orders in *Zostavax* were issued after the conclusion of bellwether discovery focused on shingles cases. It was not able to apply its summary judgment and Rule 702 orders until after that discovery was complete.

Second, an objective test, is not required for a diagnosis of gastroparesis—even if having such a test as part of the clinical diagnosis is considered the gold standard.[13] At its heart, gastroparesis is a clinical diagnosis based on a clinical assessment by a doctor trained in medical school to perform a differential diagnosis. The diagnosis is based on the physical presentation of the patient, their medical history, any available test results and ruling in or out of all possible causes of their injury. To be sure, gastroparesis may be diagnosed by testing like a gastric emptying study ("GES"). In a GES study, a patient consumes a standard meal labeled with Technetium 99m sulfur colloid following an overnight fast. Then, activity of the radioactive food is monitored at various time intervals. Medications that might interfere with the test must be withheld for at least 2 days prior to the test. The test requires a specific camera, a mobile gamma camera, and for the patient to be able to consume the standardized meal. Many plaintiffs have had GESs. But, for a variety of reasons, not all plaintiffs with a gastroparesis injury will have undergone a GES or other so-called objective tests prior to filing their lawsuit, nor are they required to. A principal reason is that GESs are not widely used in the ER setting. GESs are expensive and do not change the clinical course of treatment. Even where a doctor may prefer to have a GES done, the patient may not be able to consume the radiolabeled meal in the required 10 minutes, the severity of gastroparesis may make the patient intolerant of a GES, or the hospital may not have the resources or equipment to perform the GES. Other circumstances may not allow for a GES, such as when a patient is in the ICU or it is not possible to withhold opioids or other medications. And even when a gastric study is normal, it does not exclude the possibility that a patient has abnormal gastric motility.

Despite Defendants' insistence that a GES or other so-called objective testing are now dispositive of a legitimate injury, nowhere in the prescribing insert or marketing materials do Defendants recommend the use of such testing to diagnosis gastroparesis.[14] In fact, they say nothing at all about it. It is disingenuous for Defendants to now argue that an absence of a gastric emptying study should be dispositive of an injured Plaintiff's case. Most importantly, discovery sufficient to adequately assess each individual plaintiff's gastroparesis diagnosis requires the collection of individual medical records, depositions of the Plaintiff and his or her prescribing and treating physicians, and a thorough analysis by a retained expert. This is not an area for premature cross-cutting motion practice.

B. The Adequacy of Warnings Is Inappropriate for Early Summary Judgment Because It Must be Addressed in the Context of Plaintiff and Prescriber Discovery

Defendants have also indicated that they will ask the Court to rule on whether their warnings for these drugs were adequate as a matter of law. Such a motion is unlikely to produce any meaningful efficiencies and should only be made, if at all, after a normal period and scope of discovery on all relevant issues. Any assessment of the adequacy of Defendants' warnings accompanying these drugs requires consideration of many other issues that overlap with issues of causation and damages.

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[13] *See*, *e.g.*, *Kelley v. C.R. Bard, Inc.,* 644 F. Supp. 3d 1316 (N.D. Ga. 2022) ("The Court concludes that Rosenzweig's methodology—while no gold standard—meets Daubert's requirements.").

[14] *See* Ozempic Prescribing Insert (2023) (no mention of gastric emptying study).

Plaintiffs contend that Defendants' labels fall short of the requirements that a drug label's Warnings and Precautions "include a concise summary of the most clinically significant safety concerns from the [label] that affect decisions about whether to prescribe the drug, recommendations for patient monitoring to ensure safe use of the drug, and measures that can be taken to prevent or mitigate harm."[15] Plaintiffs further contend that the labels at issue here also do not fully "identify the risk, its consequences, and recommendations for the clinician to prevent or mitigate it, as appropriate".[16] Instead, the labels' reference to common reactions like nausea, vomiting and abdominal pain does not inform prescribers that these symptoms may be signs of life-threatening digestive dysfunction necessitating critical medical care. The labels downplay the symptoms by stating that "the majority of reports of nausea [and] vomiting ... decreased over time,"[17] minimizing these symptoms and denying prescribers and patients the opportunity to make an informed decision.[18] Lilly's warning about "gastrointestinal adverse reactions, sometimes severe" is likewise inadequate and vague: warning of an episode of severe vomiting does not, itself, warn of the risk of weeks of vomiting due to stomach paralysis, which may lead to hospitalization or death, and which may not abate after stopping the drug.

Similarly, a passing reference to "ileus" in the Post-Marketing Events section of a label (distinct from the Warnings section) does not help prescribers identify, understand, or mitigate the risk. As Defendants acknowledge, the additional reference to ileus was spurred by an FDA-initiated review, but Defendants should not have waited for the FDA to act. Manufacturers—not the FDA—are responsible for the labeling of their drugs at all times,[19] and manufacturers may not rely on the FDA to promptly ensure the adequacy of drug labeling.[20] Accordingly, as with a warning for gastroparesis, Defendants could have and should have warned of the risk of ileus in the labeling submitted for initial approval[21] and strengthened the warnings in revised labeling through the CBE process.[22] Development of a full factual record is necessary for any evaluation

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[15] FDA, Guidance for Industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements at 17 (Feb. 2013), at 13 (citing 21 C.F.R. § 201.57(a)(10)), available at https://www.fda.gov/media/71836/download (last visited July 1, 2024).

[16] *Id*.

[17] *See, e.g.,* Mounjaro Label at 6 (revised July 2023), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf (last visited 4/11/24).

[18] The listing of gastrointestinal symptoms does not warn that those symptoms can persist after cessation of the drugs. *See* Ex. B, Kalas, *et al.*, *Medication-Induced Gastroparesis: A Case Report*, J. INVESTIG. MED. HIGH IMPACT CASE REP. (Jan.-Dec.2021) (case report of patient who experienced nausea, vomiting, and bloating for weeks after discontinuing Trulicity), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (last visited July 3, 2024); Ex. C, C.T. Jones, *Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell"*, ROLLING STONE (July 25, 2023) (describing patient who experienced severe nausea both during and after she discontinued use of a GLP-1RA), *available at* https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (last visited July 3, 2024).

[19] *Wyeth v. Levine,* 555 U.S. 555, 579 (2009).

[20] *Id.* at 578-79, n.11.

[21] *In re Actos,* 2014 WL 60298, at *7 (W.D. La. Jan. 7, 2014) ("[D]efendants [can] implement stronger warning language into labeling[] by submitting stronger warning language for FDA approval…"); *see also Anderson v. Merck*, 2022 WL 17096157, at *6 (N.D. Cal. Nov. 21, 2022); *Stube v. Pfizer*, 446 F. Supp. 3d 424, 437 (W.D. Ark. 2020).

[22] *Merck v. Albrecht*, 139 S. Ct. 1668,1673 (2019) (Under the Changes Being Effected (CBE) regulation, manufacturers must "change a label without prior FDA approval… where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm." (citing 21 C.F.R. § 314.70(c)(6)(iii)(A))).

of whether Defendants have sufficiently informed prescribers and patients of "the most clinically significant safety concerns," such as gastroparesis and ileus.

An "early" motion on whether the labels are adequate as a matter of law will not be a good use of the parties' or Court's time because such adequacy cannot be evaluated in a vacuum as an abstract issue. Instead, it must be addressed in the context of individual plaintiff's claims, including, for example, failure-to-warn claims. Discovery on such claims will properly include discovery of plaintiffs' and their physicians' knowledge of and understanding of the contents of the label. That discovery should proceed alongside – because it may inform and be informed by – discovery of what Defendants themselves understood about the risks of these drugs, of their relentless and multifaceted marketing of the drugs, and how such marketing may have affected a plaintiff's or physician's understanding of the labels.[23] Rather than artificially separate or phase those related areas of discovery, the parties should proceed with comprehensive bellwether discovery.

C. Summary Judgment on Preemption Must be Decided on a Full Record

Defendants' anticipated motion for a finding of preemption also requires discovery on a full record. Preemption invariably raises fact-intensive questions that cannot be decided without extensive discovery, as courts have repeatedly held, usually after full discovery and often trial.

The affirmative defense of preemption is available only when a drug manufacturer demonstrates that it is "impossible for [it] to comply with both state and federal requirements," by showing that the FDA would not have approved a change to the drug's labeling. [24] This is a question that "cannot be resolved without knowing what information was available to the defendants."[25] The question of whether Defendants could have amended their labels based on "newly acquired information," as FDA regulations require,[26] is similarly "fact-intensive."[27] And

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Definitive causation need not be shown; only reasonable evidence of a causal association is required. *See Wyeth v. Levine,* 555 U.S.555, 571 (2009) (citing 21 C.F.R. §§ 201.80(e), 314.80(b); 73 Fed. Reg. 49605).

[23] "[T]he Pennsylvania Superior Court has recognized in the context of medications that "[g]enerally, expert medical testimony is required to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect." *Demmler v. SmithKline Beecham Corp.*, 448 Pa.Super. 425, 671 A.2d 1151, 1154 (1996), *appeal denied*, 546 Pa. 655, 684 A.2d 557 (1996). A requirement that the plaintiff must tender expert reports at the outset of a case is onerous and unrealistic. In practical terms, the testimony of treating physicians will be necessary, *Simon v. Wyeth Pharms., Inc.*, 989 A.2d 356, 375 (Pa. Super. 2009), and for a treating physician to opine about what would have been relevant to their decision-making also requires the development of a factual record. This portion of the motion will therefore be denied. *See Runner v. C.R. Bard*, 108 F. Supp. 3d 261, 271 (E.D. Pa. 2015)."*Spear v. Atrium Med. Corp.*, 621 F. Supp. 3d 553, 558 (E.D. Pa. 2022)

[24] *Merck v. Albrecht*, 139 S. Ct. 1668, 1673 (2019).

[25] *In re Incretin-Based Therapies Prod. Liab. Litig.*, 721 F. App'x 580, 583 (9th Cir. 2017) (vacating summary judgment grant).

[26] 21 C.F.R. § 314.70(c)(6)(iii)(A).

[27] *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 593 F. Supp. 3d 96, 140 (D.N.J. 2022) (citing 21 C.F.R. §§ 314.70(c)(6)(iii), 201.57(c)(6)(i)) (addressing preemption after bellwether trial).

the question of whether there is "clear evidence" that the FDA would not have approved stronger warning language necessitates extensive fact development.[28]

Specific facts are necessary to the Court's inquiry into issues of preemption. For example, the Court must know the drug at issue in the case, the warning label at issue, the injuries claimed by the Plaintiff, the alleged deficiencies on the particular warning, what was provided to the FDA and more importantly what was withheld from the FDA. Without these particulars, it is impossible for the Court to rule on every combination of drugs, labels, and injuries to truly be cross cutting. A more efficient approach is to include Plaintiff particular facts in the analysis so that the Court can issue a decision to meaningfully guide the parties.

These are only some of the issues that a preemption motion implicates. Here, it is already clear that, contrary to Defendants' assertions, they are not entitled to a ruling on preemption that the warnings in their GLP-1RA labels were adequate, as the preceding section explains.[29] For example, Plaintiffs' claims *do not* arise merely from nausea, vomiting, or constipation. Rather, Plaintiffs' claimed injuries are prolonged, life-threatening digestive dysfunction such as gastroparesis, intestinal and ileus, of which Defendants have never warned. To decide preemption questions, discovery will be necessary to establish what Defendants knew about the risks, extent, severity, and duration of these complications and whether such information was disclosed to FDA.

D. General Causation of Plaintiffs' Injuries is Well Supported and Should Not Be Decided Out of Sequence

Novo and Lilly seek early summary judgment on general causation for a combination of injuries: gastroparesis, ileus/intestinal obstruction, Cholecystitis/Gallbladder Disease (Novo only – Ozempic), and Deep Vein Thrombosis (DVT)/Pulmonary Embolism ("PE") (Novo only). But general causation of the GI injuries is well-supported both by epidemiological evidence and well-recognized mechanism of Defendants' GLP-1 drugs. General causation will not be the key issue in controversy as Defendants suggest. Both Novo and Lilly acknowledge that their GLP-1 drugs work at least in part by slowing gastric emptying—the same process—albeit to a much greater degree that occurs during gastroparesis. Indeed, studies have found more than a tripling of the risk of gastroparesis and a quadrupling of the risk of bowel obstruction with semaglutide and liraglutide.[30] Thus, the science here contrasts with the *Tylenol* MDL cited in Defendants' position

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[28] *See Wyeth*, 555 U.S. at 571 (reviewing trial record).

[29] For that argument, Defendants' position statement cited *In re Taxotere,* 462 F. Supp. 3d 650 (E.D. La. 2020), an inapposite summary judgment ruling. *See* Dkt. 85, at 14. Even in *Taxotere,* the court's ruling on the adequacy of Taxotere's warning as a matter of law applied only to the revised label after a warning was added. *Id.* at 653.

[30] *See*, *e.g.*, Novo Nordisk U.S. Ozempic Prescribing Insert ("Drug Interactions" "Ozempic delays gastric emptying. May impact absorption of concomitantly administered oral medications.")
E.g., Ex. D, Sodhi, (Gastroparesis (HR, 3.67 [95% CI, 1.15-11.9]; Bowel obstruction (HR: 4.22 [95% CI, 1.02-17.40]); *see also* Faille, et al., Incretin-Based Drugs and Risk of Intestinal Obstruction Among Patients with Type 2 Diabetes, *Clinical Pharmacology & Therapeutics*, Vol. 111 No. 1 (2021) (GLP1-RAs (dulaglutide, exenatide, liraglutide (except the weight loss formulation), and semaglutide) associated with an increased risk of intestinal obstruction when compared with use of SLGT-2 inhibitors, with highest associations observed at 1.6 years of use, (HR: 3.48, 95% CI: 1.79-6.79), Ex. E, *GLP-1 Receptor Agonists and Gastrointestinal Adverse Events*, Vol. 331, No. 10: 884-885 JAMA (2024).

statements where the science supporting the injuries was in various stages of development.[31] Causation of DVT and Gallbladder injuries are likewise well supported. The relationship between GLP-1 drugs and DVT appears to be a consequence of the GI adverse effects the drugs exert on patients, including nausea, vomiting, and diarrhea. Proposed mechanisms for DVT include diarrhea and dehydration which can lead to increases in blood viscosity.[32] Multiple meta-analyses have reported a nearly doubling or more of the risk of DVT with GLP1 drugs.[33] Likewise, meta-analyses have found that use of GLP-1 RAs were associated with increased risk of gallbladder or biliary diseases.[34]

Moreover, the discovery needed to establish general causation at Summary Judgment for multiple injuries is significant. To establish general causation at summary judgment, Plaintiffs' experts will likely be guided multiple factors utilizing complex analysis of multiple lines of evidence. One such method is a process attributed to Sir Arthur Bradford Hill as a way to distinguish causal connection from mere association. These factors are: (1) the temporal relationship between exposure and onset of symptoms or disease; (2) the strength of the association in various contexts; (3) the dose-response relationship; (4) replication of findings; (5) biological plausibility (coherence with existing knowledge); and (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of association; and (9) consistency with other knowledge. [35] Data needed to support these factors will require discovery on a broad set of subjects including regulatory submissions, clinical trials and underlying data, pharmacovigilance documents, pre-clinical studies investigating the relationship between dose and adverse effects (dose response), and the Defendants' scientific knowledge of the mechanism through which the relevant GI injuries at issue develop (biological plausibility).

For the reasons above, the just, speedy, and inexpensive administration of these proceedings does not require focusing on general causation to the exclusion of bellwether discovery.

E. The PFS Process Provides Valuable Information To Both Parties But Does Not Enable Early Disposition Except in Cases of No Proof of Use, Counterfeit or Compounded Products.

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[31] *E.g., In re Acetaminophen-ASD-ADHD Prods. Liab. Litig.*, No. 22-md-3403, 2023 WL 8711617, at *2 (S.D.N.Y. Dec. 18, 2023) ("the epidemiological evidence is highly heterogenous and major medical organizations and regulators have cautioned against drawing causal inferences from the existing body of scientific literature.").

[32] E.g., D-G Yin, et al., *Comprehensive analysis of the safety of semaglutide in type 2 diabetes: a meta-analysis of the SUSTAIN and PIONEER trials.* 60(6) ENDOCRINE J. 739 (2021).

[33] D-G Yin, et al., *Comprehensive analysis of the safety of semaglutide in type 2 diabetes: a meta-analysis of the SUSTAIN and PIONEER trials.* 60(6) ENDOCRINE J. 739 (2021) (RR 3.66, 95% CI 1.09-12.25); X-X Liao, et al., *Three new categories of hypoglycaemic agents and various cardiovascular diseases: a meta-analysis*. 47 J. CLINICAL PHARM. THERAPEUTICS 636 (2022) DVT (RR 2.12, 95% CI 1.32-3.4).

[34] *E.g.*, Ex. F, He, et al., *Association of Glucagon-Like Peptide-1 Receptor Agonist Use With Risk of Gallbladder and Biliary Diseases.* 182(5): 513-519 JAMA INTERN MED. 739 (2022).

[35] Michael D. Green, D. Michael Freedman & Leon Gordis, Reference: Guide on Epidemiology, Reference Manual on Scientific Evidence 597-606 (3d ed. 2011).

Defendants' contention that PFS responses will enable early disposition overlooks the need for individual fact and state-law inquiries, and expert opinion. Again, Defendants' suggestion that plaintiffs must have a gastric emptying studying to prove their gastroparesis injuries is flawed: Gastric emptying test results may be inconclusive, unavailable, and, depending on an expert's clinical judgment, unnecessary to prove injury.

Moreover, Defendants' suggestion of using data points in the PFS for an accelerated quasi-summary judgment process on issues such as causation and statute of limitations invites oversimplification and runs contrary to the Federal Rules of Civil Procedure. Such issues are almost always fact-intensive, contextual, or the subject of expert opinion. For example, Defendants oversimplify the causation analysis by failing to acknowledge that, under applicable state laws, Defendants' drugs need not be the sole cause of a plaintiff's injuries. Instead, plaintiffs can establish causation by demonstrating through expert opinion that Defendants' GLP-1RA drugs were a "substantial contributing factor" to their injuries. The PFS process is important for providing information relevant to those issues and others, but it is not, itself, a fair and adequate way to fully adjudicate or dispose of claims on the merits. The bellwether process and other discovery will be necessary to test the sufficiency of most plaintiffs' cases, and with rare exceptions, plaintiffs' cases will not be subject to dismissal or early summary judgment based upon their PFS alone.

Instead, the PFS process serves the valuable function of informing the bellwether process, which has significant advantages to both sides. Bellwether cases enable parties to evaluate the claims asserted, including questions of causation and liability, and for claims to be weeded out in line with test case rulings to facilitate resolution on a larger scale. A bellwether process will allow the parties to set value on pending claims, potentially dismiss claims *on the merits* without repetitive motion practice and allow for a swift and inexpensive adjudication. Cases with valid PFSs that are not selected for an early bellwether trial should be held until after the bellwether process, when their PFSs can inform decisions about resolution, remand, or further discovery. [36]

V. Conclusion

For the reasons described in this letter brief, Plaintiffs submit that Plaintiffs' proposed schedule provides the most efficient and practical approach to managing this MDL.

Respectfully submitted,

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[36] *Supra* n. 1 at §22.314 ("The judge also might consider setting several individual cases on a schedule for pretrial motions, discovery, and trial as test cases, while holding other cases or claims in abeyance.").

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